IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION *This relates to: All Actions*	No. 1:19-md-2875-RBK Hon. Robert Kugler

PLAINTIFFS' REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE OPINIONS OF AKHILESH NAGAICH, PH.D.

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INTRODUCTION

Torrent proffers Akhilesh Nagaich, Ph.D. as a regulatory, chemistry, and cGMP expert to rebut the opinions of Plaintiffs' experts Laura Plunkett and Philip Russ.[1] Dr. Nagaich opined that Torrent complied with cGMP requirements, employed adequate independent API testing, and upheld its regulatory obligations by promptly instituting a recall of its valsartan.[2] However, Dr. Nagaich's opinions are unreliable and should be excluded in their entirety due to his failure to consider critical documents or investigate threshold issues underlying his opinions.

[redacted]

Second, Dr. Nagaich failed to investigate Torrent's understanding of the risks of NDMA/NDEA generation in its valsartan API to inform his opinions on the adequacy of its risk assessment and consequent API testing.[4] [redacted][5] Dr. Nagaich's opinions lack any recognizable method and are instead based on unsupported assumptions that if Torrent did *something*, (a test, a recall), it was adequate, without ever questioning whether the information or capabilities Torrent had required it to act sooner.

LEGAL STANDARD

For expert testimony to be admissible under Rule 702, "(1) the proffered witness must be

[1] Ex. 2, Nagaich Rep. (Dec. 22, 2022), at 1, 7.
[2] Ex. 2, Nagaich Rep. (Dec. 22, 2022), at 8, 52.
[3] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 110:15–20, 105:07–21, 106:14–107:11,111:18–24, 114:20–23,118:22–119:09, 133:02–17, 130:13–22.
[4]Ex. 2, Nagaich Rep. (Dec. 22, 2022), at 8, 52; Ex. 1, Nagaich Tr. (Feb. 9. 2023), 133:02–17, 200:01–201:24, 203:14–23, 208:08–14, 209:07–24210:02–24, 215:18–216:18.
[5] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 314:07–18, 315:01–05, 315:11–317:04, 322:05–324:05.

a qualified expert; (2) the expert must testify about matters requiring scientific, technical, or specialized knowledge; and (3) the expert's testimony must 'fit' the facts of the case." *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002). The expert's opinion may not be based on "'subjective belief or unsupported speculation'" but rather must be supported by "'good grounds.'" *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 590 (1993)). The party offering the expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.,* 186 F.3d 412, 417–18 (3d Cir. 1999).

ARGUMENT

I. Dr. Nagaich's Opinion that Torrent Met Regulatory Obligations with Respect to Its Recall Should be Excluded Because He Failed to Investigate Whether Torrent Knew or Should Have Known of Nitrosamine Formation in Advance of the Recall

Inherent in Dr. Nagaich's opinion that Torrent "met its regulatory obligations with regard to patient safety by promptly and voluntarily issuing recalls as and when the company received notifications from its API supplier regarding nitrosamine contaminated API lots"[6] is the presumption that Torrent could not have issued its recall any earlier. Dr. Nagaich fails to provide a factual basis to support such a presumption and, in fact, *could not* provide such a basis because he eschewed any investigation into whether Torrent supplier ZHP tested for genotoxins *or* whether Torrent had the analytical testing capabilities to identify the presence of NDMA or NDEA in its product that should have put it on notice of nitrosamine contamination at an earlier date—thus triggering a recall at an earlier date.

A. Dr. Nagaich Never Investigated Whether ZHP Actually Tested for Genotoxins

[redacted]

[6] Ex. 2, Nagaich Rep. (Dec. 22, 2022), at 8.

[redacted]

Torrent employees knew ZHP's representations were not enough,[9] [redacted] Time and time again, courts in the Third Circuit have unequivocally held that this kind of "'subjective

[7] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 89:18–90:07.
[8] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 67:08–18. This representation applied to both valsartan API manufactured with the "old process" and "new process." *Id.*
[9] Ex. 4, Email from Dawn Chitty, TORRENT-MDL2875-00072542.
[10] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 89:18–90:07.
[11] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 90:09–18, 97:16–98:05.
[12] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 83:10–8401.
[13] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 84:13–20
[14] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 84:24–85:18.

belief or unsupported speculation'"[15] does not pass muster under *Daubert* and must be excluded as unreliable. For the same reasons, Dr. Nagaich's conclusion that Torrent "promptly" issued a recall of its valsartan is also unreliable, because that conclusion merely builds on Dr. Nagaich's blind acceptance—unsupported by any evidence—that ZHP "must" have done some testing. To the extent Torrent asserts that ZHP simply had not "discovered" the genotoxic risk at this time,[16] this assertion is unsupported by the record. [redacted] Dr. Nagaich was unable to explain why, after ZHP had already shown its statements that its API was free of genotoxins were inaccurate, it was reasonable and "prompt" for Torrent to continue to rely on those statements with respect to the old process API before ultimately recalling valsartan made with old process API months later.

B. Dr. Nagaich Never Investigated Torrent's Analytical Testing Capacity to Test for NDMA or NDEA

Dr. Nagaich rendered his opinion about the promptness of Torrent's valsartan recall without conducting any evaluation of its analytical testing capabilities during the relevant period. [redacted] For example, Dr. Nagaich:

- [redacted]

[15] *See*, *e.g.*, *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 590 (1993)).
[16] Def.'s Mem., at 18.
[17] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 84:13–20.
[18] *See*, *e.g.*, Ex. 1, Nagaich Tr. (Feb. 9, 2023), 104:15–105:06.
[19] Ex. 1, Nagaich Tr. (Feb. 9. 2023),110:15–20.

- [redacted]

Dr. Nagaich's opinions about Torrent's analytical testing capabilities are necessarily unreliable because he lacked any knowledge and failed to conduct any investigation whatsoever into what those capabilities were.[25] To be clear, Plaintiffs do not merely challenge, as Torrent suggests, Dr. Nagaich's failure to review certain specific documents; rather, Plaintiffs challenge his failure to investigate this issue *at all*. Despite this, he purports to offer opinions about the promptness of Torrent's recall and to relate the speed of its recall to patient care.[26] Yet, he never analyzed whether Torrent had the information or capabilities at its fingertips to identify the risks in its valsartan and recall it earlier than it did—information he must have in order to make a true determination of promptness. [redacted]

[20] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 105:07–21. Dr. Nagaich indicated he believed it would take a long time, possibly months, and was surprised "that they validated the assay—in three days." *Id.* at 106:22–107:11.
[21] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 106:14–21.
[22] Ex. 1, Nagaich Tr. (Feb. 9. 2023),111:18–24, 114:20–23.
[23] Ex. 1, Nagaich Tr. (Feb. 9. 2023),118:22–119:09, 133:02–17.
[24] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 130:13–22.
[25] The failure to conduct an investigation or analysis renders an expert's methodology unreliable and devoid of good grounds. *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices, & Prods. Litig.*, 509 F.Supp.3d 116, 156 (D.N.J. 2020); *see also Paramount Fin. Comms., Inc. v. Broadridge Inv. Comm. Solutions, Inc.*, 2018 WL 7815202, at *5 (E.D. Pa. Dec. 13, 2018) (excluding expert opinion as unreliable where expert failed to conduct a complete investigation); *see also Kolokowski v. Crown Equip. Co.*, 2009 WL 285957 (D.N.J. Aug. 2009) (excluding expert testimony for failure to conduct analysis of cost-benefit comparison).
[26] Ex. 2, Nagaich Rep. (Dec. 22, 2022), at 8.

[redacted]

For this reason, his recall opinions are unreliable and must be excluded.

C. Dr. Nagaich Never Investigated Whether Torrent Did Use (or Could Have) Used a Third-Party Lab to Test for NDMA or NDEA

[redacted] Nonetheless, Dr. Nagaich acknowledged during this testimony that he was aware of the FDA's inspection report of

[27] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 106:14–21.
[28] Ex. 1, Nagaich Tr. (Feb. 9. 2023),110:15–20.
[29] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 127:18–129:22, 130:13–22.
[30] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 130:13–22.
[31] *Id.*; *see also* Ex. 1, Nagaich Tr. (Feb. 9. 2023), 127:18–129:22, 13023–132:24.
[32] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 137:02–08.
[33] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 141:16–142:07, 144:11–145:09.
[34] *Id.*

ZHP's facility, during which the FDA requested that ZHP test its valsartan API for NDMA and, within a single day, ZHP was able to successfully test for NDMA in its valsartan API:

[redacted]

Dr. Nagaich's opinion that Torrent's recall of its valsartan was timely failed to account for Torrent's ability to work with third-parties, including contract laboratories, academic laboratories, or API supplier ZHP, to test its valsartan for NDMA or NDEA, thus prompting an earlier recall. Dr. Nagaich could not account for the analytical testing capabilities of any third-parties, and evaluate whether they were reasonable options that should have been used, because he never performed any investigation whatsoever into the analytical capabilities of these third-party options *or* whether Torrent even attempted to ask third-parties to perform testing. In the case of ZHP, specifically, Dr. Nagaich did not just fail to consider its analytical testing capabilities, but blatantly ignored information about testing that it actually performed on its valsartan API. Dr. Nagaich's failure to so much as investigate the analytical testing capabilities of available third parties or Torrent's attempts to use them deprives his timely recall opinion of any reliability.

II. Dr. Nagaich's Opinion that Torrent Conducted Adequate Independent Testing Should be Excluded Because Dr. Nagaich Failed to Conduct Any Investigation to Determine Whether Torrent Should Have Known of the Potential for NDMA/NDEA Formation and Tested for NDMA/NDEA Sooner

[redacted] Instead of offering mere rebuttal testimony challenging or

[35] Ex. 7, FDA Inspection Report of ZHP Facility, PRINSTON00162349-PRINSTON00162406 (emphasis added).
[36] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 40:15–20 ("my expert report is—is all about. You know, my expert report is, you know, responding to Mr. Russ; comments—and Dr. Plunkett's comments.");

disagreeing with these two experts, Dr. Nagaich's opinions go much further.[37] [redacted] Dr. Nagaich opined that "Torrent met all regulatory obligations for Valsartan API and conducted adequate independent testing of incoming API lots before using this material for manufacturing finished dose valsartan containing drug products."[40] [redacted]

Dr. Nagaich's affirmative opinion that Torrent's API testing was "adequate" lacks a reliable scientific basis because Dr. Nagaich assumed without any investigation that the baseline ANDA testing Torrent performed was all Torrent needed to do and that, because they did it, their testing was adequate. *See Elcock v. Kmart Corp.*, 233 F.3d 734, 756 (3d Cir. 2000) (excluding as unreliable testimony based on assumptions unsupported by the record). Dr. Nagaich started from the proposition that the type of testing Torrent was already performing was adequate but *never* investigated whether that was, in fact, the appropriate type of testing Torrent needed to perform to address the risks it knew or should have known about. In essence, Dr. Nagaich's testing opinions are unreliable because he cannot assess the adequacy of a testing program if he has no idea whether Torrent could have begun testing for NDMA or NDEA in its valsartan earlier than it did.

Ex. 2, Nagaich Rep. (Dec. 22, 2022), at 7 ("Assignment . . . I was asked by counsel for Torrent to review and comment on the opinions disclosed in the Russ Report and Plunket[t] Report as they relate to Torrent."). This opinion cannot be construed as a rebuttal to Plaintiff's experts: the words "independent testing" do not appear anywhere the sections of Dr. Nagaich's report labeled as responses to Plaintiff's experts. *See generally* Ex. 2, Nagaich Rep. (Dec. 22, 2022).

[37] *See Bradley v. Amazon*, 2023 WL 2574572, at *14 (E.D. Pa. Mar. 17, 2023).

[38] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 40:06–14, 54:0217, 61:15–20, 281:22–282:14.

[39] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 133:02–17, 210:02–24, 215:18–216:18.

[40] Ex. 2, Nagaich Rep. (Dec. 22, 2022), at 8, 52. Ex. 1, Nagaich Tr. (Feb. 9. 2023), 68:08–18, 171:21–173:10.

[41] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 181:10–183:04.

To be clear, the issue is not whether Dr. Nagaich reviewed this document or that document[42]—it is whether he *undertook an evaluation* of the scientific literature of NDMA and NDEA, the synthesis route of valsartan API, and Torrent's potential awareness prior to the date of the recall to determine whether it should have developed a more robust testing program to address the risk of NDMA or NDEA in its valsartan. As Dr. Nagaich repeatedly testified, he did not. The defect in Dr. Nagaich's opinion is that he did not even *attempt* to evaluate whether (1) Torrent should have been aware of the risks in the API manufacturing process; and (2) whether its testing program was sufficient to address those risks. It is the failure to engage in this investigation, which includes the failure to review information, that renders Dr. Nagaich's opinions as to API testing unreliable.

[redacted]

[redacted][43] Torrent argues that because Dr. Nagaich testified finished dose manufacturers do not have access to the full Drug Master File (DMF), his testimony establishes that Torrent did not have a reason to carry out additional testing.[44] It further asserts that Dr. Nagaich expressly stated that Torrent did *not* have information about the route of synthesis.[45] [redacted]

[redacted]

[redacted]

[42] *See* Def.'s Mem. at 7. Torrent attempts to twist Plaintiff's critiques of Dr. Nagaich into a dispute about document review. To be clear, Dr. Nagaich's inadequate document review process is merely a symptom of the larger problem, which is his failure to conduct any investigation, whatsoever, into whether Torrent knew or should have known about the risk of nitrosamine formation in its valsartan and tested accordingly,

[43] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 200:01–201:24, 203:14–23, 208:08–14, 209:07–24.

[44] Def.'s Mem., at 22–23.

[45] *Id.*

[46] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 199:20–21 ("What is—how do you define route of

[redacted]

and therefore, could not assess the risks inherent in the route of synthesis for valsartan. If Dr. Nagaich himself could not identify the risks of the route of synthesis in valsartan, he certainly cannot reliably evaluate whether *Torrent* engaged in an adequate risk analysis and addressed those risks with an adequate testing program. [redacted]

synthesis?").

[47] Ex. 1, Nagaich Tr. (Feb. 9. 2023), 200:01–201:24, 203:14–23, 208:08–14, 209"07–24

[48] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 40:06–14, 54:0217, 61:15–20, 281:22–282:14.

[49] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 133:02–17, 210:02–24, 215:18–216:18.

[50] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 284:21–22.

[redacted] To determine whether Torrent's testing program was adequate, Dr. Nagaich would first need to analyze whether Torrent was testing for foreseeable risks. However, he failed to review any scientific literature to ascertain what risks were foreseeable to Torrent and blatantly ignored the chemistry opinions of Plaintiffs' disclosed experts which explicitly identified NDMA and NDEA as risks that were foreseeable to valsartan manufacturers. This is fatal to Dr. Nagaich's testing opinions.

Dr. Nagaich's testing opinions stretch far beyond the bounds of mere rebuttal opinions. Instead, he attempts to offer affirmative expert opinions about the adequacy of Torrent's API testing program, but these opinions are devoid of any scientific validity. Dr. Nagaich starts from

[51] *See, e.g.*, Ex. 5, Hecht. Rep. (July 6, 2021), at 20 ("The use of nitrite should have raised a gigantic *RED FLAG* that nitrosamines could be present in the API… Factor 2 should have raised a *RED FLAG* for the potential formation of nitrosamines. The contamination of dimethal formamide with dimethylamine or the formation of dimethylamine during the process was foreseeable and should have been evaluated."); Ex. 6, Najafi Dec. (Oct. 31. 2022), at 24–25 ("During this manufacturing process, the triethylamine hydrochloride that is used in synthetic step #4 gets nitrosated and undergoes elimination of HNO followed by hydration and elimination of water and acetalhyde to give rise to diethylamine which then easily gets nitrosated again to form NDEA… … Once again, all the ingredients for the formation of NDMA are present".

[52] Ex. 5, Hecht. Rep. (July 6, 2021), at 21; Ex. 6, Najafi Dec. (Oct. 31, 2022), at 16 ("The final drug substance should also be tested for impurity.").

[53] Ex. 5, Hecht. Rep. (July 6, 2021), at 6; 21; Ex. 6, Najafi Dec. (Oct. 31, 2022), at 16.

the assumption that the testing Torrent had was all it needed to do without so much as conducting an investigation as to whether Torrent should have known of the impurities in its valsartan and, as a result, conducted additional testing. He conducted no analysis of the chemistry underlying the foreseeability of the risks of NDMA or NDEA generation, including as articulated by Plaintiffs' disclosed experts. For these reasons, his testing opinions are unreliable and must be excluded in their entirety.

III. Dr. Nagaich's Opinion that cGMP Compliance Required Only Compliance with the Valsartan Monograph Should be Excluded as Unreliable Because, in Reaching that Opinion Dr. Nagaich Contradicts Himself and Ignores Section 5.60 of the General Notices

Prior to his deposition, Dr. Nagaich did not review, consider, or rely upon the USP General Notices and Requirements, Section 5.60 ("General Notices").[54] [redacted]

Expert opinions cannot be "self-contradictory" because such opinions are "logically ill-

[54] *See generally* Ex. 2, Nagaich Rep. (Dec. 22, 2022); Ex. 1, Nagaich Tr. (Feb. 9, 2023).
[55] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 314:07–18.
[56] *Compare* Ex. 1, Nagaich Tr. (Feb. 9, 2023), 314:07–18 *with* 322:05–324:05.
[57] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 221:05–222:09.
[58] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 315:01–05.
[59] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 314:07–18.

formed." *In re TMI Litig.*, 911 F. Supp. 775, 787 (M.D. Pa. 1996) (quotations omitted). Yet, neither Dr. Nagaich nor Torrent[60] could explain Dr. Nagaich's failure to consider the General Notices or identify any authority as to why Dr. Nagaich's reversal of course midway through his testimony was (or could ever be) reliable. Instead, Torrent merely tries to skim over this reversal, picking the version of Dr. Nagaich's interpretation that most favors Torrent, and arguing for its correctness. However, both Dr. Nagaich's own statements about the General Notices and the language of the General Notices, when considered as a whole, undermine that interpretation.

In trying to shore up Dr. Nagaich's assertion that the only quality expectation for manufacturers is the monograph, while the General Notices are merely optional, Torrent zeroes in on a single word[61] in the General Notices, arguing that that single word indicates the document is permissive, rather than mandatory.[62] [redacted]

[60] Torrent claims that Dr. Nagaich *did* consider the General Notices, pointing to testimony by Dr. Nagaich in which Plaintiff's counsel showed the General Notices to Dr. Nagaich and questioned him about them. Dr. Nagaich rendered his cGMP opinions in his report *before* he was ever shown this document by Plaintiff's counsel, *see generally* Ex. 2, Nagaich Rep. (Dec. 22, 2022), and further changed course midway through his deposition indicating that he was unprepared to even discuss it with Plaintiff's counsel. *Compare* Ex. 1, Nagaich Tr. (Feb. 9, 2023), 314:07–18 *with* 322:05–324:05.

[61] Though Torrent takes pains to distinguish the General Chapters from the General Notices, it asks the Court to construe the term "should" as used in section 5.60 of the General Notices in accordance with an "FAQ" webpage specific to the General Chapters. *See* Def.'s Mem., at 13–14 (citing USP, Frequently Asked Questions, #11 https://www.usp.org/frequently-asked questions/identifying-official-text). However, if the Court is to take USP at its word, the FAQs, including the definitions provided therein "should not be construed as an official interpretation of USP text or be relied upon to demonstrate compliance with USP standards or requirements." *See* USP, Frequently Asked Questions, https://www.usp.org/frequently-asked-questions (last visited April 20, 2023). As described above, when read in full, the General Notices function as compliance expectations that set conditions for the application of the USP which, according to Dr. Nagaich himself, rank higher than the USP monograph and, as such, the nonbinding FAQ guidance (which Dr. Nagaich also never considered) for an entirely separate document has no bearing on whether they should be deemed mandatory or permissive. *See Bunkowski v. Oberg Indus.*, 787 F.3d 190, 200 (3d Cir. 2015) (explaining that interpretation of a word requires consideration of the whole document and its purpose).

[62] Def.'s Mem., at 13–14.

[redacted]

However, it is clear from the overarching purpose of the General Notices and the language of the document as a whole, that the General Notices are mandatory. [redacted] Specifically, section 5.60 of the General Notices provides that "Tests for the presence of impurities and foreign substances are provided to limit such substances to amounts that are unobjectionable under conditions in which the article is *customarily*

[63] *See* Ex. 1, Nagaich Tr., (Feb. 9, 2023), 313:03–19.
[64] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 313:10–19 (quoting Ex. 3. General Notices § 5.60) (emphasis added).
[65] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 315:01–05.
[66] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 314:07–18. Torrent asserts that Dr. Nagaich did not testify that the "general chapters of the USP . . . rank higher than and interpret the monograph and that 'manufacturers must comply with them.'" Def.'s Mem., at 13 (quoting Pl.'s Opening Mem., at 12). As the above testimony shows, however, Dr. Nagaich said exactly that.
[67] *Id.*

employed"[68] but on reviewing this section, [redacted] This reversal of opinion, made only in the face of evidence unfavorable to Torrent, is unreliable under Rule 702.

In opining that the only quality expectation on manufacturers is the USP monograph—and that Torrent therefore was cGMP compliant simply because it followed the monograph—Dr. Nagaich entirely failed to consider the General Notices and then directly contradicted his opinions on the General Notices when he realized that his earlier opinion was unfavorable to Torrent. Dr. Nagaich's opinion on this point is therefore unreliable and must be excluded in its entirety.

[68] Ex. 3, General Notices, § 5.60.
[69] Ex. 1, Nagaich Tr. (Feb. 9, 2023), 315:11–317:04.
[70] *Compare* Ex. 1, Nagaich Tr. (Feb. 9, 2023), 314:07–18 *with* 322:05–324:05.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the opinions of Akhilesh Nagaich, Ph.D., in their entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on April 25, 2023 , a true and correct redacted copy of the foregoing was filed and served via the court's CM/ECF system, and an unredacted version was served on the court and the Defense Executive Committee via email.

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